JUN - 8 2000

K000836

510(k) Summary

Bionx Implants Inc.'s

BioSorbPDX™ Bioabsorbable Fixation System

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
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Bluebell, PA 19422

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President and Chief Executive Officer
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Bionx Implants Ltd.
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Quality Manager
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FIN-33721 Tampere
Finland
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Date prepared: June 7th, 2000

Name of the Device: BioSorbPDX™ Bioabsorbable Fixation System

Common or Usual Name:

Bioabsorbable Craniofacial Bone Plates and Plate Fasteners

Classification Name: Bone Plate and fasteners (Product Code 76 JEY)

Predicate Devices:

1. Bionx Implants, Inc. BioSorbFX™ 1.5/2.0 Bioabsorbable Fixation System ("BioSorbFX™ 1.5/2.0 System") (K982139)
2. Bionx Implants, Inc. BioSorbFX™ O/M 2.0/2.4 Bioabsorbable Fixation System ("BioSorbFX™ O/M 2.0/2.4 System") (K982721)
3. Walter Lorenz Surgical, inc. LactoSorb® Trauma Plating System (K974309, K971870, K960988)

Intended Use

BioSorbPDX System™ is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton. Specifically, the device is indicated for use in treating fractures of the craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas; comminuted fractures of the frontal sinus wall; orbital floor fractures; trauma of the midface or craniofacial skeleton and reconstructive procedures of the midface or craniofacial skeleton. In the BioSorbPDX™ System an instrument set is also included containing bone drills, bone taps, screwdrivers and bending instrument.

BioSorbPDX™ System is not intended for use in and is contraindicated for: 1) the mandible; 2) full load bearing procedures; 3) areas with active infection; or 4) patient conditions, including blood supply limitations, insufficient quantity or quality of bone or latent infections.

Device Description and Principles of Operation

The BioSorbPDX™ System consists of a series bioabsorbable plates with various shapes (e.g., rectangular, straight line, X-, Y-, L-, C-shape), styles (e.g., straight edge and scalloped edge) and with a varying number of countersunk holes. The countersunk holes in the plates are sized to be secured to the midface or craniofacial skeleton with bioabsorbable fasteners (i.e., screw).

Properly used, in the presence of adequate immobilization, absorbable BioSorbPDX™ System implants maintain accurate alignment of bone fracture and osteotomies after open reduction.

Technological Characteristics and Substantial Equivalence

As noted above, the BioSorbPDX™ System is made from polylactide-glycolide copolymer. As a bone fracture or osteotomy gains strength during healing, the BioSorbPDX™ System implants gradually lose their strength during 6-8 weeks. Biodegradation takes place within one year.

The BioSorbPDX™ Bioabsorbable Fixation Systems consists of various plate configurations, which are attached to the bone by threaded fasteners (i.e., screws) of various lengths. The models of plates are almost identical and substantially equivalent with the plates of the previously cleared BioSorbFX™ 1.5/2.0 System (K982139). The design of diameter 1.5 and 2.0mm fasteners are identical with the previously cleared BioSorbFX™ 1.5/2.0 System (K982139).).

The copolymer derived from L-lactide and glycolide ("PLGA" or "PLA/PGA") used in the BioSorbPDX™ System is substantially equivalent with the material used in the Walter Lorenz Surgical, Inc. LactoSorb® Trauma Plating System ("LactoSorb®") (K974309, K971870 and K960988).

The BioSorbPDX™ System instrument set consists of stainless steel (400 Series) bone drill, bone tap, screwdriver and bending instrument for plate. This instrument set is the same as used with previously cleared BioSorbFX™ 1.5/2.0 System (K982139).

The Bionx Implants Inc., BioSorbPDX™ 1.5/2.0 System and BioSorbFX™ 1.5/2.0 Bioabsorbable Fixation System (K982139) and Walter Lorenz Surgical, Inc. LactoSorb® Trauma Plating System (K974309, K971870 and K960988) have the same intended use and principles of operation and very similar design characteristics. The minor technical differences between the BioSorbPDX™ System and the predicate devices do not raise any new questions of safety or effectiviness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2000

Bionx Implants Incorporated
C/O Ms. Tuija Annala
Quality Manager
Bionx Implants Limited
P.O. Box 3
FIN-33721 Tampere
FINLAND

Re: K000836
Trade Name: BioSorbPDX™ Bioabsorbable Fixation System
Regulatory Class: II
Product Code: JEY
Dated: December 23, 1999
Received: March 14, 2000

Dear Ms. Annala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K000836

Device Name: BioSorbPDX Bioabsorbable Fixation System

Indications for Use:

BioSorbPDX System ™ is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton. Specifically, the device is indicated for use in treating fractures of the craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas; comminuted fractures of the frontal sinus wall; orbital floor fractures; trauma of the midface or craniofacial skeleton and reconstructive procedures of the midface or craniofacial skeleton. In the BioSorbPDX™ System an instrument set is also included containing bone drills, bone taps, screwdrivers and bending instrument.

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(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-off Susan Runner

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000836